



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,315	10/29/2001	Robert V. Farese JR.	UCAL-105CIP2	1732

24353 7590 09/17/2004

BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER

BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
----------	--------------

1632

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/040,315		FARESE ET AL.	
	Examiner		Art Unit	
	Valarie Bertoglio		1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1632

DETAILED ACTION

After further consideration, the previous office action mailed 12/17/2003 has been vacated and replaced with the instant office action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2-5, drawn to a non-human animal having decreased endogenous DGAT expression resulting from a defect in the endogenous DGAT gene without a transgene encoding and exogenous DGAT, classified in class 800, subclass 8.
- II. Claims 6 and 7, drawn to drawn to a non-human animal characterized by having a transgene disrupting the naturally occurring, endogenous DGAT gene and further comprising a transgene comprising an exogenous DGAT coding sequence, classified in class 800, subclass 8.
- III. Claims 8 and 9, drawn to non-human animal characterized by having a transgene encoding an exogenous DGAT without a disruption in an endogenous DGAT gene, classified in class 800, subclass 8.
- IV. Claims 12 and 13, drawn to cells in vitro having a disrupted endogenous DGAT locus without an exogenous DGA transgene, classified in class 435, subclass 325.
- V. Claim 14, drawn to cells in vitro having a disrupted endogenous DGAT locus and further comprising a coding sequence for a human DGAT polypeptide, classified in class 435, subclass 325.
- VI. Claims 15-17 and 19, drawn to a screening assay for modulators of DGAT activity using human DGAT protein in vitro, classified in class 435, subclass 15.

Art Unit: 1632

- VII. Claims 18 and 19, drawn to a screening assay for modulators of DGAT activity using mouse DGAT protein in vitro, classified in class 435, subclass 15.
- VIII. Claims 17 and 19, drawn to a screening assay for modulators of DGAT activity using human DGAT expressing cells, without a disruption in the endogenous DGAT gene, classified in class 435, subclass 7.21.
- IX. Claims 18 and 19, drawn to a screening assay for modulators of DGAT activity using mouse DGAT expressing cells, without a disruption in the endogenous DGAT gene, classified in class 435, subclass 7.21.
- X. Claims 17 and 20-23, drawn to a screening assay for modulators of DGAT activity using cells, in vivo, expressing human DGAT, without a disruption in the endogenous DGAT gene, classified in class 800, subclass 3.
- XI. Claims 18,20,21 and 23, drawn to a screening assay for modulators of DGAT activity using mouse DGAT expressing cells in vivo without a disruption in the endogenous DGAT gene, classified in class 800, subclass 3.
- XII. Claims 26 and 28, drawn to an in vitro assay for screening candidate agents for modulatory activity of human DGAT expression using a human DGAT polypeptide expression cassette, classified in class 435, subclass 6.
- XIII. Claims 26 and 29, drawn to an in vitro assay for screening candidate agents for modulatory activity of mouse DGAT expression using a mouse DGAT polypeptide expression cassette, classified in class 435, subclass 6.
- XIV. Claims 26 and 28, drawn to an in vitro cellular assay for screening candidate agents for modulatory activity of human DGAT expression using cells comprising

Art Unit: 1632

a human DGAT polypeptide expression cassette, without a disruption in the endogenous DGAT gene, classified in class 435, subclass 7.21.

XV. Claims 26 and 29, drawn to an in vitro assay for screening candidate agents for modulatory activity of mouse DGAT expression using cells comprising a mouse DGAT polypeptide expression cassette, without a disruption in the endogenous DGAT gene, classified in class 435, subclass 7.21.

XVI. Claims 27 and 28, drawn to an in vivo assay for screening candidate agents for modulatory activity of human DGAT expression using a non-human animal comprising a human DGAT polypeptide expression cassette, without a disruption in the endogenous DGAT gene, classified in class 800, subclass 3.

XVII. Claims 27 and 29, drawn to an in vivo assay for screening candidate agents for modulatory activity of human DGAT expression using a non-human animal comprising a mouse DGAT polypeptide expression cassette, without a disruption in the endogenous DGAT gene, classified in class 800, subclass 3.

Claim 1 link(s) inventions I-III. The restriction requirement to the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory

Art Unit: 1632

double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 10 and 11 link(s) inventions IV and V. The restriction requirement to the linked inventions is subject to the nonallowance of the linking claim(s), claims 10 and 11. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 15 and 16 link(s) inventions VI-XI. The restriction requirement to the linked inventions is subject to the nonallowance of the linking claim(s), claims 15 and 16. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims

Art Unit: 1632

of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 24 and 25 link(s) inventions XII-XVII. The restriction requirement to the linked inventions is subject to the nonallowance of the linking claim(s), claims 24 and 25. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are patentably distinct because the products have different structures and different functions. Invention I is drawn to a non-human animal with a defect in the endogenous DGAT gene. Invention II is drawn to a knockout DGAT animal further comprising an exogenous DGAT gene. Invention III is drawn to an otherwise normal non-human animal with increased

Art Unit: 1632

endogenous DGAT expression resulting from an extra DGAT coding sequence. The animals differ genetically, differ in the level of endogenous and exogenous DGAT expression and have different uses with different purpose. Furthermore, the search of any of Inventions I-III together would require undue burden.

Inventions I and IV are patentably distinct because the non-human animals can be used for in vivo assays to determine the in vivo role of DGAT while the cells can be used in vitro in differential expression assays to determine genes modulated by DGAT expression or activity. The structure and function of the non-human animals and of the cells are different. It would require undue burden to search Inventions I and IV together.

Inventions I and V are patentably distinct because the non-human animals can be used for in vivo assays to determine the in vivo role of DGAT while the cells can be used in vitro to determine to conservation of DGAT activity or to determine the effects of altered DGAT activity on gene expression in cells. The animals and cells differ genetically. The structure and function of the non-human animals and of the cells are different. It would require undue burden to search Inventions I and IV together.

Inventions I-III are patentably distinct from each of Inventions VI-IX because Inventions I-III are drawn to non-human animals that are not used in the methods of Inventions VI-IX. The methods do not require the animal and the animal does not require the methods. It would require an undue burden to search any of the animals of Invention I-III with any of the methods of any of Inventions VI-IX.

Invention I and Inventions X and XI are patentably distinct because the animals of Invention I can be used to assess the function of DGAT in vivo using animals with a disrupted

DGAT gene while the methods of Inventions X and XI contact animals expressing DGAT to identify modulators of DGAT activity. The methods of Invention X and XI do not require the animals of Invention I. The methods can be carried out using other animals such as those overexpressing DGAT. It would require an undue burden to search the animal of Invention I with any of the methods of either of Inventions X or XI.

Inventions I-III are patentably distinct from each of Inventions XII-XV because Inventions I-III are drawn to non-human animals that are not used in the methods of Inventions XII-XV. The methods require a DGAT expression cassette not required for the animals. The methods do not require the animals and the animals do not require the methods. It would require an undue burden to search the animals of any of Inventions I-III with any of the methods of any of Inventions XII-XV.

Invention I and Inventions XVI and XVII are patentably distinct because the animals of Invention I can be used to assess the function of DGAT in vivo using animals with a disrupted DGAT gene while the methods of Inventions XVI and XVII use animals comprising a DGAT expression cassette to identify modulators of DGAT expression. The methods of Invention XVI and XVII do not require the animals of Invention I. The methods can be carried out using other animals such as those comprising a DGAT expression cassette. It would require an undue burden to search the animal of Invention I with any of the methods of either of Inventions XVI or XVII.

Inventions II and III are patentably distinct from Invention IV. The non-human animals of Invention II and II comprises an exogenous or extra copy of the endogenous DGAT gene. The cells of Invention IV have a disrupted endogenous DGAT locus and do not have additional copies of the DGAT gene. The animals of Inventions II and III and the cells of Invention IV are

genetically and functionally distinct and have different uses. Furthermore, it would require undue burden to search either of Inventions II or III together with Invention IV.

Inventions II and V are patentably distinct because the non-human animals can be used for in vivo assays to determine the in vivo role of DGAT while the cells can be used in vitro to determine to conservation of DGAT activity or to determine the effects of altered DGAT activity on gene expression in cells. The structure and function of the non-human animals and of the cells are different. It would require undue burden to search Inventions II and V together.

Invention II and Inventions X and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods of Inventions X and XI can be carried out using animals other than those of Invention II, including animals with a functional endogenous DGAT gene.

Invention II and III are patentably distinct from Inventions XVI and XVII because the animals of Inventions II and III can be used to assess the functional conservation of DGAT or to identify functional modulators in vivo using animals comprising a transgene encoding a DGAT polypeptide while the methods of Inventions XVI and XVII use animals comprising a DGAT expression cassette to identify modulators of DGAT expression. The methods of Invention XVI and XVII do not require the animals of Inventions II or III. The methods can be carried out using other animals such as those comprising a DGAT expression cassette. It would require an undue

burden to search the animal of either of Inventions II or III with any of the methods of either of Inventions XVI or XVII.

Inventions III and V are patentably distinct because the non-human animals can be used for in vivo assays to determine the in vivo effects of overexpressing DGAT while the cells can be used in vitro to determine to conservation of DGAT activity. The animals and cells differ genetically in that the animals have a disrupted endogenous DGAT gene and the cells do not. The structure and function of the non-human animals and of the cells are different. It would require undue burden to search Inventions III and V together.

Invention III and Inventions X and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods of Inventions X and XI can be carried out using animals other than those of Invention III, including animals with a functional endogenous DGAT gene.

Invention IV and V are patentably distinct because the products have different structures and different functions. Invention IV is drawn to a cell with a defect in the endogenous DGAT gene. Invention V is drawn to a knockout DGAT cell further comprising an exogenous DGAT gene. The cells differ genetically, differ in the level of endogenous and exogenous DGAT expression and have different uses with different purpose. Furthermore, the search of Inventions IV and V together would require undue burden.

Inventions IV and V are patentably distinct from Inventions VI and VII because Inventions IV and V are drawn to cells that are not used in the methods of Inventions VI or VII. The methods of Inventions VI and VII require a mouse or human DGAT protein and do not require the cells of Inventions IV or V. It would require an undue burden to search the cells of Invention IV or V with either of the methods of Inventions VI or VII.

Invention IV and Inventions VIII and IX are patentably distinct because the cells of Invention I can be used to assess the function of DGAT using cells with a disrupted DGAT gene while the methods of Inventions VIII and IX require contacting cells expressing DGAT to identify modulators of DGAT activity. The methods of Inventions VIII and IX do not require the cells of Invention IV. The methods can be carried out using other cells such as those overexpressing DGAT. It would require an undue burden to search the cells of Invention IV with the methods of either of Inventions VIII or IX.

Inventions IV and V are patentably distinct from the methods of Inventions X and XI because Inventions IV and V are drawn to cells with a disruption in the DGAT gene and further comprising a gene encoding human DGAT (Invention V) while the methods of Inventions X and XI are drawn to using an animal expressing exogenous DGAT. The cells can be used in methods other than those of Invention X and XI such as in differential expression profiling in vitro while the in vivo methods of Invention X and XI do not require the cells of Inventions IV and V and can be carried out using animals that do not have a disruption in the endogenous DGAT locus. It would require an undue burden to search the cells of Inventions IV or V with the methods of either of Inventions X or XI.

Art Unit: 1632

Inventions IV and V are patentably distinct from Inventions XII-XVII because the cells of Invention IV can be used to determine the role of endogenous DGAT on gene expression profiles in vitro and the cells of Invention V can be used to assess the functional conservation of human DGAT or to screen for activity modulators while the methods of Inventions XII-XVII are used to screen for modulators of DGAT expression. The methods of Invention XII-XVII do not require the cells of Invention IV or V. It would require an undue burden to search the cells of Inventions IV or V with the methods of any of Inventions XII-XVII.

Invention V and Inventions VIII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods of Inventions VIII and IX can each be carried out using cells other than those of Invention V, including cells with a functional endogenous DGAT gene.

Inventions VI and VII are patentably distinct because each is practiced using a different polypeptide. Invention VI requires a human DGAT polypeptide that differs in structure and potentially in function from the mouse DGAT polypeptide required by Invention VII. The modulators of the polypeptides of each of the Inventions will be different. It would require an undue burden to search the Inventions VI and VII together.

Invention VI and VII are patentably distinct from the methods of Inventions VIII-XI because the methods of the methods of each of inventions VI and VII are materially different and plurally independent from the methods of each of Inventions VIII-XI and each is practiced with

Art Unit: 1632

materially different process steps and technical considerations and requires materially distinct protocols and reagents. Methods VI and VII use a DGAT polypeptide, directly, in vitro, while Inventions VIII and XI use a cell expressing a DGAT protein and Invention X and XI use animals expressing a DGAT polypeptide. Neither of Inventions VI or VII is necessary for any of the methods of Inventions VIII-XI. It would require an undue burden to search the methods of either of Inventions VI or VII with the methods of any of Inventions VIII-XI.

The methods of each of inventions VI-XI are materially different and plurally independent from the methods of each of Inventions XII-XVII because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The purpose of the methods of Inventions VI-XI is to screen for functional modulators. The purpose of the methods of Inventions XII-XVII is to screen for expression modulators. No method of Inventions VI-XI is necessary for any of the methods of Inventions XII-XVII. It would require an undue burden to search the methods of any of Inventions VI-XI with the methods of any of Inventions XII-XVII.

Inventions VIII and IX are patentably distinct because each is practiced using cells with different structure as the cells of each invention comprise a gene encoding a structurally different polypeptide. Invention VIII requires using a cell expressing a human DGAT polypeptide that differs in structure and potentially in function from the cell expressing a mouse DGAT polypeptide required by Invention IX. The modulators of the polypeptides of each of the inventions will be different. It would require an undue burden to search the Inventions VIII and IX together.

Inventions VIII and IX are patentably distinct from the methods of Inventions X and XI because the methods of the methods of each of inventions VIII and IX are materially different and plurally independent from the methods of Inventions X and XI and each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Methods of Inventions VIII and XI use a cell expressing a DGAT protein while Inventions X and XI use animals expressing a DGAT polypeptide. Neither of Inventions VIII or IX is necessary for the methods of Inventions X and XI. It would require an undue burden to search the methods of either of Inventions VIII or IX with the methods of any of Inventions X or XI.

Inventions X and XI are patentably distinct because each is practiced using animals with different structure, as the animals of each Invention comprise a gene encoding a structurally different polypeptide. Invention X requires using an animal expressing a human DGAT polypeptide that differs in structure and potentially in function from the animal expressing a mouse DGAT polypeptide required by Invention XI. The modulators of the polypeptides identified by each of the inventions will be different. It would require an undue burden to search the Inventions X and XI together.

Invention XII and XIII are patentably distinct because each is practiced using a different polypeptide expression cassette. Invention XII requires a human DGAT polypeptide expression cassette that differs in structure the mouse DGAT polypeptide expression cassette required by Invention XIII. The expression modulators identified in each of the Inventions may be different. It would require an undue burden to search the Inventions XII and XIII together.

Art Unit: 1632

Inventions XII and XIII are patentably distinct from the methods of Inventions XIV-XVII because the methods of each of inventions XII and XIII are materially different and plurally independent from the methods of each of Inventions XIV-XVII. Each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Methods XII and XIII use a DGAT expression cassette, directly, in vitro, while Inventions XIV and XV use a cell comprising a DGAT expression cassette and Invention XVI and XVII use animals comprising a DGAT expression cassette. Neither of Inventions XII or XIII is necessary for any of the methods of Inventions XIV-XVII. It would require an undue burden to search the methods of either of Inventions XII or XIII with the methods of any of Inventions XIV-XVII.

Invention XIV and XV are patentably distinct because each is practiced using a cell comprising a different polypeptide expression cassette. Invention XIV requires a cell comprising a human DGAT polypeptide expression cassette that differs in structure from the mouse DGAT polypeptide expression cassette required by Invention XV. The expression modulators identified in each of the Inventions may be different. It would require an undue burden to search the Inventions XIV and XV together.

Inventions XIV and XV are patentably distinct from the methods of Inventions XVI and XVII because the methods of each of inventions XIV and XV are materially different and plurally independent from the methods of each of Inventions XVI and XVII. Each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Methods XIV and XV use cells comprising a DGAT expression cassette and Inventions XVI and XVII use animals comprising a DGAT expression cassette.

Art Unit: 1632

Neither of Inventions XIV or XV is necessary for any of the methods of Inventions XVI or XVII.

It would require an undue burden to search the methods of either of Inventions XIV or XV with the methods of any of Inventions XVI or XVII.

Invention XVI and XVII are patentably distinct because each is practiced using an animal comprising a different polypeptide expression cassette. Invention XVI requires an animal comprising a human DGAT polypeptide expression cassette that differs in structure from the mouse DGAT polypeptide expression cassette required by Invention XVII. The expression modulators identified in each of the Inventions may be different. It would require an undue burden to search the Inventions XVI and XVII together.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

Art Unit: 1632

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio
Examiner
Art Unit 1632

MICHAEL WILSON
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Michael Wilson', with a long horizontal line extending to the right.